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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
087533-095	07/26/95	TOPALIAN	S 2026-4205

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EXAMINER
CAPUTA, A

ART UNIT	PAPER NUMBER
1645	17

DATE MAILED: 04/29/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

Office Action Summary

Application No.
08/533,895

Applicant(s)
Topalian et al.

Examiner
Anthony C. Caputa

Group Art Unit
1645



☒ Responsive to communication(s) filed on 9 Feb 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 3-30, 56, 61, and 64 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 3-30, 56, 61, and 64 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 9 and 16

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

Information Disclosure Statement

2. The information disclosure statement filed May 19, 1997 (see Paper No. 9) and applicants' supplemental amendment filed 2/9/98 (Paper No. 16) were considered.

The examiner requests applicants provide a year and month for Genebank Accession Nos. J03581; U101873; Y00819; M27160, and EMBASE Accession Number M33295 as listing on the IDS filed May 19, 1997 (see Paper No. 9)

Claim Rejections - 35 USC § 112

3. Claims 3-30, 56, 61, and 64 are rejected under 35 USC 112, first paragraph for the reasons of record.

Applicants assert that the references by Lazar et al. and Burgess et al. are not relevant to amino acids changes and immunogenicity in a peptide since these references are related to heparin binding and mitogenic activity. Applicants arguments are noted. However, it is the Examiner's position that since these references demonstrate that a single amino acid change substitution will affect the biological activity of a protein it is reasonable for a skilled artisan in the art to conclude modifications of a peptide will affect the biological activity of said peptide.

Furthermore, applicants argument is not persuasive since the art at the time of filing as exemplified by Salgaller et al. sets forth single amino acid or even side chain substitutions abrogate immunogenicity (T cell cytotoxicity). Additionally, Parker et al. concludes while the P2 and P9 residues of a nonamer peptide are of prime importance for peptide binding to HLA-A2, other peptide positions including P2, P3, P5-P7 and P9 were important for stable binding (see

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abstract). Finally, Englehard states “studies have identified peptides that fail to bind or bind poorly despite the presence of an optimal motif” (see page 18; Column 1).

Since:

- 1) the quantity of experimentation necessary of the claimed invention requires screening a multitude of peptides
- 2) the art teaches of the unpredictability of single amino acid substitutions have on a protein (i.e. Salgaller et al., Burgess et al., and Lazar et al);
- 3) peptides fail to bind or bind poorly despite the presence of an optimal motif (see Englehard);
- 4) peptide positions including P2, P3, P5-P7 and P9 of nonamer peptide are important for stable binding (see Parker et al)

a skilled artisan would be forced into undue experimentation to practice the claimed invention (See *in re Wands*, 858 F.2d 731 8 USPQ2d 1400 (Fed. Cir. 1988)).

Applicants urges the specification provides sufficient teachings for one skilled in the art to practice the claimed invention. These arguments are not considered persuasive. The decisional law has held the mere recitation in the specification of a broad concept does not necessarily provide a sufficient basis for broadly claiming it. See Ex parte Gardner 157 USPQ 162 (Bd. Pat. Appls and Interf. 1967), In re Cavallilo, 127 USPQ 202 (CCPA 1969). The fact that the terms in a claim are the same as those in the specification does not prevent the claims from being rejected as unduly broad if they define subject matter not described to be the actual invention by means of adequate representative samples. See in re Lund, 153 USPQ 625 (CCPA 1967). In the instant case one skilled in the art would be forced into undue experimentation to practice the claimed invention. Due to the unpredictable nature of which modifications are useful (See Lazaret al., Burgess et al., Sallgaller et al., Parker et al. and

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Englehard) and the multitude of derivatives encompassed in the claimed invention one skilled in the art can not practice the invention as claimed absent undue experimentation.

4. The prior rejection of claim 3 under 35 USC 112, second paragraph is withdrawn in view of applicants' amendment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Anthony C. Caputa, whose telephone number is (703)-308-3995. The examiner can be reached on Monday-Thursday from 8:30 AM-6:00 PM. The examiner can be reached on alternate Fridays. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703)-308-0196. Papers related to this application may be submitted to Art Unit 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The Fax number is (703)-308-4242.

Anthony C. Caputa, Ph.D.

27 April 1998



ANTHONY C. CAPUTA
PRIMARY EXAMINER